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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,233	10/21/2003	Stefan A. Sharpe	PD01642	4939

24265 7590 10/09/2007

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,233	SHARPE ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10,11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks filed 2 July 2007 have been filed and made of record.

Applicants argue on the grounds that the 103(a) rejection was insufficient due to the absence of each and every element being taught by the cited references.

A reconsideration of the 103(a) rejection has been determined.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-6, 8, 10, 11, and 14 are pending for examination. Claims 7, 9, 12-13, and 15-20 are cancelled.

Claim Rejection-35 U.S.C.§ 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, 10-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eccleston et al., (Rheological Behavior of Nasal Sprays in Shear and Extension, Drug Development and Industrial Pharmacy, volume 26, issue 9 (2000), pages 973-983, printed page 1) in view of Pinier et al. (USPN 5,572,321), and further in view of Nasonex® Product Information, Schering Corporation, Kenilworth, NJ 07033, copyright (1997), printed page 1-4.

Eccleston et al. teach rheological profiles of commercial corticosteroid nasal spray suspensions (Beconase®, Nasacort®, Flixonase®, and Nasonex®) were compared using shear and extensional techniques. Thixotropy/shear thinning was investigated (Carri-Med CSL100, concentric cylinder geometry) by (a) the generation of flow curves at low (100 sec^{-1}) and high (1200 sec^{-1}) maximum shear rates and (b) determination of equilibrium shear viscosities at constant shear rates of 10 sec^{-1}, 100 sec^{-1}, or 1200 sec^{-1}. Extensional properties, on which droplet breakup and size depend, were examined using digital camera photography of droplet evolution and the length any trailing filament formed when the suspension was extruded from a 10-ml syringe at 500 μl/min. All the nasal suspensions were shear thinning and were also thixotropic to varying degrees. The absence of significant thixotropic recovery at short times (5 min) for all the sprays implies that thixotropy is not necessarily the controlling factor for prolonged residence of the spray in the nasal cavity, but rather that it is the high viscosities present in all four sprays, even after structure breakdown. Preliminary extensional flow data identified differences among the four sprays, with extensional filament lengths increasing in the same rank order as the lowest shear rate (10 sec^{-1}) equilibrium viscosities (abstract only).

This teaching of Eccleston et al. would coincide with the central issue of claimed invention, which is drawn to the time to form a secondary structure via the disclosure, ' *The absence of significant thixotropic recovery time at short times (5 min) for all the sprays implies that thixotropy is not necessarily the controlling factor for prolonged residence of the spray in the nasal cavity.*' The time to form secondary structure of a thixotropic formulation is judged in relation to the administration of an intranasal spray solution to the nasal cavity; the solution's therapeutic effect being determined by it's level of contact with intranasal passages due to the

thixotropic and viscous properties. The reasoning concentrates upon thixotropy but more so upon the high viscosity in all four sprays tested. Eccleston et al. does teach extensional properties, on which droplet breakup and size depend, [with examination] using digital camera photography of droplet evolution and the length any trailing filament formed when the suspension was extruded from a 10-ml syringe at 500-microliters/minute.

Eccleston et al. teach the varying degrees of thixotropy for all four formulations and the absence of significant thixotropic recovery (secondary structure) at short times for all sprays.

Eccleston does not specifically teach back-scattered light by using a particle vision and measurement probe.

However, Pinier et al. does teach a device for measuring the luminous intensity scattered by thin films of colloidal media. It is more particularly intended for submicron grain-size analysis by photon correlation, and comprises a device for measuring the luminous intensity scattered by thin films (16) of colloidal media. The invention includes a monochromatic luminous source (2); a converging optical system (4) focusing the source on the thin film to be analyzed; at least one photosensitive detector (5; 5'; 5"; 5'") detecting the light scattered or backscattered by the thin film; and a system (60, 70) for processing the signal coming from photodetector(s) (5) (abstract only).

Pinier et al. teach a transparent object, i.e., glass as a refractor but also as an analyzer of the thickness of a sample (column 5, lines 41-47)

Pinier et al. teach the application of viscosity measurements on thixotropic liquids (column 2, lines 43-45).

Accordingly, Pinier et al. teach measurements of the viscosity drawn to a continuous phase (column 4, lines 51-53). In light of Pinier et al teaching measurements of viscosity drawn to a continuous phase, it would be obvious to arrive at the conclusion that video imaging could be interchangeable with the process of measuring viscosity drawn to a continuous phase over time. Time-lapse photography is an instance where an image is captured but this instant series of time-lapse photographs could readily be converted to video imaging via a quick succession process. The objective of the instant invention is to measure thixotropy recovery (secondary structure). Thus, it would be apparent to the skilled artisan that imaging and the conversion of video imaging would occur in view of measuring viscosity drawn to a continuous phase over time.

Pinier et al. does teach an aqueous sample being used for analysis and determination on said device.

Pinier et al. does not disclose the aqueous sample as being an intranasal formulation.

However, Nasonex® Official Site teaches Nasonex as being comprised of mometasone furoate (pg 1, Description, 2nd ¶).

Nasonex® Official Site teaches 0.05% w/w in the pharmaceutically acceptable carrier comprising microcrystalline cellulose, carboxymethylcellulose sodium NF, and additionally the humectant glycerin (pg 1, Description, 2nd ¶).

Nasonex® Official Site teaches 100 mg of suspension containing mometasone furoate monohydrate equivalent to 50 micrograms of mometasone furoate calculated on the anhydrous basis.

Nasonex® Official Site is indicated for the treatment of nasal symptoms and is not indicated to be comprised of alcohol (see Description, column 1, paragraphs 1-3).

Thus, it would be *prima facie* obvious to the skilled artisan at the time of invention to at once recognize a reasonable expectation of success via the combining or incorporating together of Eccleston et al. Pinier et al, and the Nasonex Product Information insert. There would be instant motivation to combine references Eccleston et al. and Pinier et al. based on Eccleston et al. specific teachings of distinct thixotropy recovery methodology and experimentation and Pinier et al. measurements of such thixotropic movement, i.e., the viscosity drawn to a continuous phase in time. However, in accordance, the Nasonex Product Information insert provides the most essential motivation based on the limitations drawn to specific parameters and descriptions of said nasal formulation. Instant claims 2-6, 8, 10-11; and 14 are made obvious over the disclosure in the Nasonex Product Information insert.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

10/1/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER